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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,507	04/22/2004	Kishore Udipi	P1422 US (2650/98)	7359

28390 7590 10/01/2007

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER
OU, JING RUI

ART UNIT	PAPER NUMBER
3709	

NOTIFICATION DATE	DELIVERY MODE
10/01/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/829,507	UDIPI ET AL.	
	Examiner	Art Unit	
	Jing Rui Ou	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/22/2004, 08/16/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Search Notes*.

DETAILED ACTION

1. This action is responsive to the non-provisional application filed on Apri 22, 2004, Claims 1-40 are pending. Claims 1, 21,29, and 38 are independent.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-6 and 8-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,918,929 in view of Pacetti (WO 03/022323 A1). US. Pat No. 6,918,929 teaches all the limitations of claims 1-6 and 8-40 but fails to teach using polysulfone as one of the polymers to form a polymeric coating onto a medical device or a stent. However, Pacetti explicitly discloses that polysulfone can be used to form the polymeric coating. The motivation or suggestion for using polysulfone as one of the polymers to form a polymeric coating

onto a medical device or a stent is that polysulfone has relatively high crystallinity can maintain its crystallinity in an aqueous environment. Polysulfone is rigid, has high melting temperatures, and are minimally affected by solvent penestration. Therefore, polysulfone can serve as a rate-reducing coating onto a medical device (Paras. [0021]-[0022]).

4. Claim 7 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 and 7 of U.S. Patent No. 6,918,929 in view of Pacetti (WO 03/022323 A1), and further in view of Chang et al (US Pat. No. 4,157,960). US. Pat No. 6,918,929 and Pacetti teach all the limitations of claim 7 but fail to disclose that polysulfone has a molecular weight between 10,000 Daltons and 100,000 Daltons. However, Chang et al explicitly discloses that polysulfone has a molecular weight between 10,000 Daltons and 100,000 Daltons (Chang et al, Col. 8, lines 4-7). The suggestion/motivation for doing so would have been that a molecular weight less than 100,000 Daltons is suitable for film or fiber formation (Chang et al, Col. 8, lines 1-7).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-2, 6, 12, 14-15, 19, 29, and 33-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz (US Pub. No.: 2003/0235602).

In regard to claim 1, Schwartz discloses a system for treating a vascular condition, comprising: a catheter; a stent coupled to the catheter, the stent including a stent framework (Para.[0007]); a polymeric coating disposed on the stent framework, wherein the polymeric coating (carrier coating, Paras.[0025] and [0027]) comprises a blended matrix of a polysulfone and a styrenic block copolymer (Para.[0005], [0045], and [0052]); and a therapeutic agent in contact with the blended matrix (Para.[0025]).

In regard to claim 2, the catheter includes a balloon used to expand the stent (Para.[0007]).

In regard to claim 6, the therapeutic agent is dispersed within the blended matrix of the polysulfone and the styrenic block copolymer (Paras.[0026], [0045], [0052], and [0062]) .

In regard to claim 12, the therapeutic agent is positioned between the polymeric coating and the stent framework (Para.[0027]).

In regard to claim 14, the blended matrix of the polysulfone and the styrenic block copolymer provides a controlled elution rate for the therapeutic agent (Para.[0055]).

In regard to claim 15, the therapeutic agent is selected from the group consisting of an antirestenotic drug, an antisense agent, an antineoplastic agent, an antiproliferative agent, an antithrombogenic agent, an anticoagulant, an antiplatelet agent, an antibiotic, an anti-inflammatory agent, a steroid, a gene therapy agent, a therapeutic substance, an organic drug, a pharmaceutical compound, a recombinant

DNA product, a recombinant RNA product, a collagen, a collagenic derivative, a protein, a protein analog, a saccharide, a saccharide derivative, a bioactive agent, a pharmaceutical drug, and a combination thereof (Para.[0033]-[0037]).

In regard to claim 19, the system further comprises a primer coating (barrier coating, Para.[0026]) disposed on the stent framework between the stent framework and the polymeric coating (Paras.[0026-0028]).

In regard to claim 29, a drug-polymer coated stent, comprising: a stent framework (Para.[0007]); and a polymeric coating (carrier coating, Paras.[0025] and [0027]) disposed on the stent framework, wherein the polymeric coating comprises a blended matrix of a polysulfone and a styrenic block copolymer (Para.[0005], [0045], and [0052]); and a therapeutic agent contacting the polymeric coating (Para.[0025]).

In regard to claim 33, the therapeutic agent is selected from the group consisting of an antirestenotic agent, an antisense agent, an antineoplastic agent, an antiproliferative agent, an antithrombogenic agent, an anticoagulant, an antiplatelet agent, an antibiotic, an anti-inflammatory agent, a steroid, a gene therapy agent, a therapeutic substance, an organic drug, a pharmaceutical compound, a recombinant DNA product, a recombinant RNA product, a collagen, a collagenic derivative, a protein, a protein analog, a saccharide, and a saccharide derivative.

In regard to claim 34, the therapeutic agent is dispersed within the blended matrix of the polysulfone and the styrenic block copolymer (Para.[0033]-[0037]).

In regard to claim 35, the therapeutic agent is positioned between the polymeric coating and the stent framework (Para.[0027]).

In regard to claim 36, the stent further comprises a primer coating (barrier coating, Para.[0026]) disposed on the stent framework between the stent framework and the polymeric coating (Paras.[0026-0028]).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (US Pub No.: 2003/0235602 A1) in view of Chang et al (US Pat. No.: 4,157,960).

In regard to claim 7, Schwartz discloses a system for treating a vascular condition, comprising: a catheter; a stent coupled to the catheter, the stent including a stent framework (Paras. [0005] and [0029]); a polymeric coating (carrier layer, Para. [0027]) disposed on the stent framework, wherein the polymeric coating comprises a blended matrix of a polysulfone and a styrenic block copolymer (Paras. [0027] and [0045]); and a therapeutic agent in contact with the blended matrix (Para.[0028]).

Schwartz does not appear to disclose that the polysulfone has a molecular weight between 10,000 Daltons and 100,000 Daltons.

However, Chang et al explicitly discloses that the molecular weight of the polysulfone is generally at least about 10,000 and less than about 500,000, and is frequently less than about 100,000 (Col. 8, lines 4-7).

Schwartz and Chang et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Schwartz and Chang et al before him or her, to modify the system of Schwartz to include polysulfone which has a molecular weight between 10,000 Daltons and 100,000 Daltons.

The suggestion/motivation for doing so would have been that a molecular weight less than 500,000 Daltons is suitable for film or fiber formation (Col. 8, lines 1-7).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jing Rui Ou whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571)272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRO

JOSEPH DEL SOLE
SUPERVISORY PATENT EXAMINER
9/25/07